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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

JOEL S. GREENBERGER ET AL.

Serial No. 09/292,056

Filed: April 14, 1999

Art Unit: 1744

Patent Examiner:

William H. Beisner

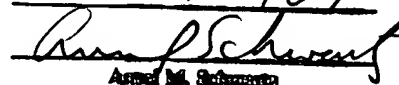
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) METHOD AND APPARATUS  
) FOR HOLDING CELLS  
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)  
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)  
)

Pittsburgh, Pennsylvania 15213

October 12, 2007

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**CERTIFICATE OF MAILING**  
I hereby certify that this correspondence  
is being deposited with the U.S. Postal  
Service as first class mail in an envelope  
addressed to: Commissioner for Patents,  
P.O. Box 1450, Alexandria, VA 22313-  
1450 on 10/12/07  
  
Arnold M. Schwartz  
Registration No. 30,587

PETITION UNDER RULE 1.181

Petitioners petition the Assistant Commissioner to rescind the Restriction Requirement issued by the Examiner regarding the above-identified patent application in the Action dated April 3, 2007, and now placed in final status by the Examiner in the Action dated September 20, 2007.

There are many reasons why this Restriction Requirement should be rescinded.

This is the second time that the Examiner has placed a Restriction Requirement on the above-

identified patent application. The first time, the Examiner rescinded the Restriction Requirement. Furthermore, the pending claims have limitations that are similar, and patentability in regard to these limitations will be revealed in a common patentability search. In addition, during the approximate six years since the previous Restriction Requirement was rescinded, there have been about 100 prior art references considered by the Examiner, either indirectly or directly, by being cited by the Examiner as a basis of rejection of the claims, and were all overcome. It is respectfully submitted the relevant prior art has been exhausted and there are most likely no other better references available to consider for further search in regard to the restriction of the claims by the Examiner. The one new reference the Examiner cites in the latest Action, has also been cited in a co-pending sister continuation application of the above-identified patent application, further supporting the position that a patentability search of the pending claims only yields the same art. The double patenting rejection raised by the Examiner only supports the rescission of the Restriction Requirement.

More specifically, on April 24, 2001, the Examiner issued a Restriction Requirement regarding the above-identified patent application, a copy of which is attached as Exhibit A. This Restriction Requirement identified nine different inventions. On July 24, 2001, Petitioners filed an Election with Traverse electing Invention IX and requesting the Examiner to rescind the Restriction Requirement in regard to Inventions I, II, IV, V, VI, VII and IX. In the Office Action dated October 5, 2001 (a copy in relevant part is attached as

Exhibit B), the Examiner rescinded the Restriction Requirement in part and Inventions I-VI and IX were rejoined. Furthermore, in this Office Action, the Examiner cited art rejections against all the pending claims as a whole.

Prosecution then proceeded with many Office Actions and Information Disclosure Statements being filed, where many different references were cited against the claims as a whole, until the Office Action of July 5, 2005, where there were no further art rejections, only a 112 rejection. To reiterate, at this point in time, all the claims had been allowed over the applied art of record, and in regard to the many Office Actions and prior art rejections that were cited against the claims, the prior art rejections were cited essentially as a whole against all the pending claims. Subsequently, the 112 rejection was argued, and in a last conversation with the Examiner regarding the 112 rejection, at about the end of 2006, it was expected that the application would be allowed.

On April 3, 2007, the second Restriction Requirement, and the basis for this Petition, was issued by a new Examiner who was assigned to the above-identified patent application. Petitioners responded with an Election with Traverse, and on September 20, 2007, the Examiner issued an Office Action, placing the Restriction Requirement into final status, citing a new reference against the claims and raising a double patenting rejection in

regard to sister continuation application, 10/114,892. As an aside, the previous 112 rejection was obviated.

The second Restriction Requirement should be rescinded simply because the first Restriction Requirement was rescinded in regard to the subject claims.

In regard to the sister continuation application, it was filed after the first Restriction Requirement was rescinded in part. The claims of the sister continuation application were associated with Invention VII identified in the above-identified patent application. The first Restriction Requirement was not rescinded in regard to Inventions VII and VIII.

First, in regard to the sister continuation application, after it was determined by the Examiner that the claims of the sister continuation application were a separate Invention VII as identified in the first Restriction Requirement, the new Examiner has now decided after about five years of co-pendency that the pending claims of the sister continuation application are substantially the same as the elected Claims 114-123 of the above-identified patent application, even though all the claims in the sister continuation application have the limitation of a robotic arm while none of the elected Claims 114-123 have the limitation of a robotic arm. Basically, the Examiner has totally disregarded the established prosecution history of the

above-identified patent application and ignored the U.S. Patent and Trademark Office's own previous positions. For this reason, the second Restriction Requirement should be rescinded.

Second, the new Examiner has rejected the active claims of the sister continuation application over the same reference, Funakubo, that the Examiner has now rejected elected Claims 114-123 of the above-identified patent application. The fact that the Examiner has cited the same reference against claims that were determined previously to be a separate invention, resulting in a sister continuation application being filed, and the elected claims in the above-identified patent application, only emphasizes the fact that no additional or different searching is required to determine the patentability of all the other claims identified in the second Restriction Requirement. This same reference should also be applicable against all the subject claims. The second Restriction Requirement should be rescinded for this reason.

Third, the very basis that the Examiner states for the double patenting rejection, that the claims of the sister continuation application in the elected claims of the above-identified patent application both "disclose conventional structures for automating a culture process that includes image analysis" is also the basis for rescinding the Restriction Requirement for all the claims identified in the second Restriction Requirement. (This was also the basis of Petitioners' successful argument to rescind the first Restriction Requirement.) In fact, it is respectfully submitted that the Examiner cannot have it both ways. The Examiner

is placing the Restriction Requirement on the claims of the above-identified patent application by taking the position that the various claims form distinct inventions, and then literally in the next page of the Office Action stating that the elected claims are substantially similar to claims that were already restricted out and are even more distinct than any of the other claims identified in the second Restriction Requirement. The very argument of double patenting by the Examiner regarding the sister continuation application is in direct conflict and negates the position the Examiner takes as to the second Restriction Requirement, and for this reason, the second Restriction Requirement should be rescinded.

Besides the fact that the independent claims in the above-identified patent application disclose conventional structures for automating the culture process that include image analysis," as the Examiner states in regard to the double patenting rejection, they also include the limitation of a closed system in which each individual cell of the plurality of cells can be individually examined over time. See independent Claim 1 of Invention I, independent Claim 51 of Invention I, independent Claim 57 of Invention II, independent Claim 70 of Invention II, independent Claim 74 of Invention III, independent Claim 75 of the Invention I, independent Claim 80 of Invention IV and independent Claim 114 of Invention V. Independent Claims 1, 51, 57, 70, 74, 75 and 114 also have the limitation of determining the state of said individual cell of a plurality of cells over time. In regard to the pending claims involving means for automatically determining the state of the individual cell of the plurality of

cells over time, as was explained in regard to the now obviated 112 rejection which focused on what structure was associated with the "means" language, it includes an imaging mechanism.

Any search regarding patentability is constrained by these limitations, which results in the claims of Inventions I-V of the second Restriction Requirement being limited to the same search. This is already proven by the simple fact that the Examiner has cited the same reference, Funakubo, against the sister continuation application in the elected claims having the limitation of "a closed system" in which the cells are located, and examining each individual cell of a plurality of cells over time - "analyzing the state of each cell of the cells over time," as found in elected Claim 114. For this reason, the second Restriction Requirement should be rescinded.

If the Restriction Requirement is allowed to stand, Petitioners will be required to file many additional divisionals and after the applications are allowed, pay many additional maintenance fees, resulting in exorbitant additional expense.

Furthermore, since it is believed the prior art has been exhausted with so many references already reviewed in the above-identified patent application, the Examiner will simply cite Funakubo, or one of the references already made of record in the above-identified patent application, against the divisional applications. It should be noted that Funakubo, it is

respectfully submitted, does not teach or suggest examining each individual cell of a plurality of cells over time, but instead is concerned with tracking the proliferation of a colony of monoclonal antibodies; and does not teach or suggest a dynamically controlled closed environment, which many of the claims require.

It is also reiterated, because so many references have been considered and made of record of the above-identified patent application, the relevant prior art has been identified and reviewed. No further searching is needed. All that further searching will produce is art that is no better than references that have already been overcome by the Petitioners.

It is respectfully submitted the Examiner cannot ignore about six years of prosecution, including the identification of about 100 prior art references which reveal the patentability of all the claims, and basically start prosecution from the beginning. Petitioners already had to file the sister continuation application because of the first Restriction Requirement, which the new Examiner now indirectly states was not required. The U.S. Patent and Trademark Office must be required to stand by its decisions as correct and require that prosecution be consistent.

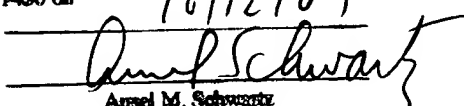
Petitioners respectfully petition that the second Restriction Requirement be rescinded. All of the claims have substantially similar limitations, if not identical, and the



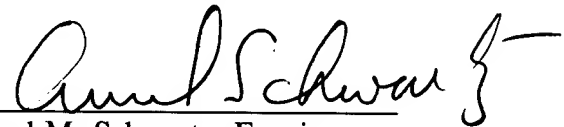
patentability search regarding the elected claims will reveal the patentability of all the other claims. There is already a first Restriction Requirement which was rescinded in regard to the subject claims. The Examiner's own arguments regarding double patenting support the Restriction Requirement being rescinded.

A check in the amount of \$130.00 is enclosed for payment of this Petition. The Patent Office is hereby authorized to charge Deposit Account No. 19-0737 for additional fees that may be due with this paper. A duplicate copy of this Petition is attached.

**CERTIFICATE OF MAILING**  
I hereby certify that this correspondence  
is being deposited with the U.S. Postal  
Service as first class mail in an envelope  
addressed to: Commissioner for Patents,  
P.O. Box 1450, Alexandria, VA 22319-  
1450 on

10/12/07  
  
Ansel M. Schwartz  
Registration No. 30,587

Respectfully submitted,

By   
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Pittsburgh, PA 15213  
(412) 621-9222

Attorney for Petitioners

**EXHIBIT A**



**UNITED STATES DEPARTMENT OF COMMERCE**  
**United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/292,056 04/14/99 GREENBERGER

J PITT-1DIV

EXAMINER

HM12/0424

ANSEL M SCHWARTZ  
ONE STERLING PLAZA  
201 N CRAIG STREET SUITE 304  
PITTSBURGH PA 15213

SOLUAYA, J

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/292,056

Applicant(s)  
Greenberger et al

Examiner  
Jehanne Souaya

Art Unit  
1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 9, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 47-123 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1 and 47-123 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, 47-50, 94, 96, 103, and 104, drawn to an apparatus for holding a plurality of cells comprising:
    - a mechanism for incubating a plurality of cells which includes wells
    - a mechanism for determining the state of cells
    - an imaging mechanism,classified in class 435, subclass 287.1.
  - II. Claims 57-64 and 70, drawn to an apparatus for growing cells comprising:
    - a mechanism for incubating cells which includes wells
    - a tracking mechanism
    - an identifying mechanism which identifies division and differentiation,classified in class 435, subclass 288.4.
  - III. Claim 74, drawn to an apparatus for holding a stem cell comprising:
    - a mechanism for incubating the cell
    - a mechanism for determining a desired state of the cell
    - a mechanism for introducing media to the cell,classified in class 435, subclass 286.4.

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IV. Claims 75-79, drawn to an apparatus for holding a plurality of cells comprising:

- a mechanism for incubating the plurality of cells
- a controlling mechanism for exchanging media
- a mechanism for determining the state of the cells
- a mechanism for automatically testing fro predetermined biological variables,

classified in class 435, subclass 287.3.

V. Claims 80-81, 86-95, 97, and 99-100, drawn to an apparatus for holding cells comprising:

- a mechanism for incubating the cells
- a robotic arm
- a mechanism for controlling the environment about each cell,

classified in class 436, subclass 286.1.

VI. Claims 51-56, drawn to an apparatus for incubating and determining the state of cells comprising:

- a mechanism for incubating cells
- a mechanism for determining the state of cells
- a mechanism for determining a biological event
- a mechanism for determining a stage of cells based on a metabolic process,

classified in class 435, subclass 287.1.

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VII. Claims 65-69, 73, 82-84, 98, 101, 107, 108, and 110, drawn to an apparatus and method for developing desired processes for control of a cell comprising:

- a mechanism for incubating a plurality of cells
- a robotic arm
- a mechanism for determining which materials enhance a desired process,
- a diagnostic mechanism for ascertaining the occurrence of a biological event
- a determining mechanism which determines how to insert transgenes
- an imaging mechanism

classified in class 435, subclass 286.1 (apparatus) and 435, subclass 375 (method).

VIII. Claims 71-72, 85, 105-106, and 109, drawn to a method for growing cells, classified in class 435, subclass 383.

IX. Claims 114-123, drawn to an apparatus for culturing and analyzing cells comprising:

- a biochamber
- a liquid handling system
- an image recognition system
- a stage for supporting the biochamber
- a system controller
- a microscope,

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classified in class 435, subclass 289.1.

2. The inventions are distinct, each from the other because of the following reasons: The inventions of group VII and groups I-VI and IX are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the apparatus of group VII does not contain the mechanism for determining the state of cells of groups I, III, IV, VI the tracking mechanism of group II, the mechanism for controlling the environment about each cell of group V, the mechanism for determining a stage of cells based on a metabolic process of group VI, the mechanism for automatically testing for predetermined biological variables of group IV, the stage for supporting the biochamber of group IX, or the system controller of group IX. The subcombinations of groups I, IV, V have separate utility such as apparatus for holding cells, the subcombination of group II has separate utility as an apparatus for growing cells, the subcombination of group, the subcombination of group III has separate utility as an apparatus for holding a single stem cell, the subcombination of group VI has separate utility as an apparatus for incubating and determining the state of cells, the subcombination of group IX has separate utility as an apparatus for culturing and analyzing cells.
3. The inventions of groups I-VI and IX are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are



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shown to be separately usable. In the instant case, the invention of group II has separate utility such as an apparatus for growing cells, the invention of group III has separate utility such as an apparatus for holding a single stem cell, the invention of group VI has separate utility such as an apparatus for determining the state of cells, the invention of group IX has separate utility as such as an apparatus for culturing and analyzing cells. Although the inventions of groups I, IV and V are all drawn to apparatus for holding cells, each apparatus contain features which confer separate utility to each apparatus. The apparatus of group V contains the limitation of a mechanism for controlling the environment about each cell, whereas the apparatus of groups I and IV are not drawn to such a limitation. The apparatus of group IV contains the limitations of a controlling mechanism for exchanging media and mechanisms for automatically teasing for predetermined biological events, whereas the apparatus of groups I and V are not drawn to such limitations. See MPEP § 806.05(d).

4. The invention of groups II and VIII are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method of group VIII does not require the imaging mechanism of group II, therefore, the apparatus required to practice the invention of group VIII is different from the apparatus of group II. Furthermore, the apparatus of group II can be used to image cells.

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5. The inventions of groups I, III-VII and IX and the invention of group VIII are patentably distinct as the apparatus of groups I, III-VII and IX are not needed to practice the invention of group II. Specifically, the apparatus of group I contains an imaging mechanism which is not required to practice the method of group VIII. The apparatus of groups III, IV, and VI contain a mechanism to determine the state of cells which is not required to practice the method of group VIII. The apparatus of groups V and VII contain a robotic arm which is not required to practice the invention group VIII. Such steps in the method of group VIII can be practiced by hand. The apparatus of group IX contains a stage for supporting the biochamber and a system controller which are not required to practice the method of group VIII.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-IX, restriction for examination purposes as indicated is proper.

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9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

11. Applicant should note that claims 102 and 111-113 have not been addressed in the above restriction. These claims are dependent on canceled claims.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya  
Patent examiner

*Jehanne Souaya*  
*April 23, 2001*

  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600

**EXHIBIT B**



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

*John*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/292,056    04/14/99    GREENBERGER

J    PITT-1DIV

ANSEL M SCHWARTZ  
ONE STERLING PLAZA  
201 N CRAIG STREET SUITE 304  
PITTSBURGH PA 15213

HM12/1005

EXAMINER
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SQUAYA, J

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 10/05/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/292,056

Applicant(s)  
Greenberger et al

Examiner  
Jehanne Souaya

Art Unit  
1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 26, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 47-123 is/are pending in the application.
- 4a) Of the above, claim(s) 65-69, 71-73, 82-85, 101, 102, and 105-113 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 47-64, 70, 74-81, 86-100, 103, 104, and 114-123 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

Art Unit: 1655

## **DETAILED ACTION**

### ***Election/Restriction***

The claims for groups I-VI and IX have been rejoined. Accordingly, an action on the merits follows for claims 1, 47-64, 70, 74-81, 86-100, 103, 104, and 114-123.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 57, 74, 80, 86-88, 90, 93, 99, 100, 114, 115, and 118-123 are rejected under 35 U.S.C. 102(b) as being anticipated by Maruhashi *et al.* (U.S. Patent 5,403,735 (Apr. 4, 1995)).

Maruhashi teaches a method and apparatus for culturing and detecting cells (abstract). Maruhashi teaches that prior art methods of testing a cell culture for cell viability, growth rate or other diagnostic means have the disadvantages of requiring the opening of a closed and sterile culture system to test, liquid used for testing cannot be returned to the culture because of stains used to test viability, and that such staining means are not very reliable and do not provide any information as to the ratio of viable cells (col. 2 line 48-col. 3 line 12). Maruhashi teaches means for culturing and observing cellular cultures where the means for culturing and means for detecting are in fluid communication so that the culture system does not need to be opened and